

## REMARKS

Claims 1-21 were in issue. By this amendment, claims 1-3, 8-10, and 15-17 have been amended, no claims have been canceled, and no claims have been added. Accordingly, claims 1-21 are presented and at issue. No new matter has been added.

### **The §101 Rejection**

The Examiner has rejected claims 1-6, 8-13, and 15-20 under 35 U.S.C. §101 as covering non-statutory subject matter. Applicant respectfully traverses this rejection with respect to the claims as amended.

The Examiner's analysis of these claims is not in accordance with present law. First, the treatment of "means plus function" claims" in the present context has been defined by the Federal Circuit as follows:

"This court, in banc, has determined that claims written in means-plus-function format contain statutory subject matter *even if functional phrases of the means limitations recite mathematical calculations*. See *Alappat*, 33 F.3d at 1544, 31 U.S.P.Q.2D (BNA) at 1558. Therefore, the claims of the [patent in issue] do not wholly preempt the use of mathematical calculations because the claims are limited to the structure disclosed in the specification and equivalent structures for performing the claimed functions." *Schlafl v. Caro-Kann Corporation*, 1998 U.S. App. LEXIS 8250; 1998-1 Trade Cas. (CCH) P72,138; 40 Fed. R. Serv. 3d (Callaghan) 790 (Fed. Cir. 1998) (emphasis added).

In the present case, embodiments for implementing the invention are described as a neural network (shown in FIG. 1 and described on pp. 5-6), appropriate programming, and implementation in either hardware or software (see p. 14).

Second, the test for patentable subject matter was recently clarified by the Federal Circuit:

"Today, we hold that the transformation of data ... by a machine through a series of mathematical calculations into a final [output] constitutes a practical application of a mathematical algorithm, formula, or calculation, because it produces "a useful, concrete and tangible result" ...." *State Street Bank & Trust Co. v. Signature Financial Group, Inc.*, \_\_ F.3d \_\_ (Fed. Cir. 1998).

In *State Street*, the “useful, concrete and tangible result” was a final share price, calculated from transformation of data representing discrete dollar amounts.

While the claims as originally presented (particularly the “Beauregard” style claims 15-21, which are directed to a computer program) met the criteria for statutory subject matter, Applicant has clarified these claims to explicitly recite the use of a computer. Hence, the claims cover training a computer-implemented artificial neural network (ANN), applying the ANN to input data characterizing at least one test peptide-like molecule, and analyzing each applied test peptide-like molecule using the ANN to generate a prediction of a relative binding affinity for each test peptide-like molecule, and output such prediction. The output constitutes a “useful, concrete and tangible result” – information about the test molecule not previously known.

### **The §102 Rejection**

The Examiner has rejected claims 1-21 under 35 U.S.C. §102(b) as being anticipated by each of the references to Metfessel, Riis, Holley and Kneller. Applicant respectfully traverses this rejection with respect to the claims as amended.

The independent claims as amended require *generation of a prediction of a relative binding affinity*. For example, claim 1 requires “analyzing each applied test peptide-like molecule using the ANN to generate a prediction of a relative binding affinity for each test peptide-like molecule, and outputting such prediction.” The cited art does not teach at least this element. For Class I major histocompatibility complex (MHC) molecules, the affinity of the bound peptides largely determines the stability of the expressed class I molecules and their recognition by immuno-surveillant cytotoxic T-cells. To the best of Applicants’ knowledge, artificial neural network analysis has not been successfully applied to prediction of binding affinities of biologically active peptides and peptide mimetics.

All 4 cited references teach using various statistical analyses and neural networks to predict protein *structure* (not binding affinity) from the primary, secondary, and some tertiary *structural* characteristics of a *protein* sequence. Such sequences are typically much longer than peptides (e.g., peptides eluted from class I MHC molecules reveal that they are short, usually 8-10 amino acids long). Applicants’ reading of these 4 references does not find any mention of predicting binding

affinity. Moreover, prediction of structure does not inherently provide information regarding binding affinity. For example, it is well known that a conservative amino acid change in an amino acid sequence can provide for a similar tertiary structure but a different binding affinity. Accordingly, these references lack an element claimed by Applicants, and thus fails as a §102 reference.

Accordingly, Applicant submits that none of the references, alone or in combination, anticipate or make obvious the invention as presently claimed. Applicant submits that this case is now in condition for allowance. Therefore, Applicant respectfully requests reconsideration and reexamination of the present application and allowance of the case at an early date.

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DEPARTMENT OF COMMERCE

Respectfully submitted,

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